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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/815,102

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Andrew A. Conway

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AGILENT TECHNOLOGIES INC.

INTELLECTUAL PROPERTY ADMINISTRATION,LEGAL DEPT.

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EXAMINER

RIGGS II, LARRY D

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

02/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary

Application No.

10/815,102

Applicant(s)

CONWAY, ANDREW A.

Examiner

LARRY D. RIGGS II

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-18 and 21-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-8, 11-18 and 21-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicant's amendments filed 28 April 2008 are acknowledged and entered.

Status of Claims

Claims 9, 10, 19 and 20 are cancelled. Claims 1-8, 11-18, 21-23 are currently pending and under consideration.

Withdrawn Rejections/Objections

The objection of the disclosure in the Office action mailed 06 February 2008 is withdrawn in view of the amendments filed 28 April 2008.

The objection to claims 1, 11 and 21, in the Office action mailed 06 February 2008 is withdrawn in view of the amendments filed 28 April 2008.

The rejection of claims 1-50 under 35 U.S.C. 101, in the Office action mailed 13 April 2007 is withdrawn in view of the amendments filed 03 October 2007.

The rejection of claims 1-20 under 35 U.S.C. 102(a) over Liao et al., in the Office action mailed 13 April 2007 is withdrawn in view of the declaration filed 03 October 2007.

The rejection of claims 21-50 under 35 U.S.C. 103(a) over Liao et al. in view of Kasif et al., in the Office action mailed 13 April 2007 is withdrawn in view of the declaration filed 03 October 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11-18 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in lines 3-4 of the "analyzing" step and claim 11 in lines 6-7, recite the limitation "markers exhibiting particular homozygous pairs of alleles more frequently than would occur randomly". The metes and bounds of the limitation are unclear. The specification and claims do not provide a clear and precise definition of what encompasses "more frequently than would occur randomly". One skilled in the art would be unclear as to what the metes and bounds of the limitation may encompass.

Claim 1 in line 25, claim 11 in line 18 and claim 21 in line 20, recite the limitation "whether said marker is autozygous and whether said marker is not autozygous". The metes and bounds are unclear. One skilled in the art would not understand how a marker, defined as a genetic sequence in the specification, page 7, line 18, can be or not be autozygous. An organism carrying two alleles and can be autozygous but it is unclear how a single sequence can be autozygous.

Claim 1 in lines 33-35, recite the limitation "selecting...at least one contiguous region likely to contain a recessive allele associated with said genetic disease or trait". The metes and bounds of the limitation are unclear. The previously described "merged scores" indicate non-overlapping contiguous regions of markers. There has been no

previous indication, i.e. scores, cluster of markers, a contiguous region of markers, etc. of what would enable one skilled in the art to determine if a contiguous region is "likely to contain a recessive allele associated with said genetic disease or trait".

Response to Arguments

Applicants point to the specification page 3, lines 1-8 to provide a clear and precise definition of the limitation "more frequently than would occur randomly". Wherein the applicant indicates that analyzing the actual and estimated genotype data to find a region in the genome of affected people includes markers exhibiting particular homozygous pairs of alleles more frequently than would occur randomly. Likewise applicant suggest the definitions of autozygous and not autozygous makes the instant limitation clear.

Applicants argue that particular scores of markers is an indication of whether an individual with particular markers may or may not be autozygous.

Applicant's arguments are not persuasive.

Restating what groups are tested for homozygous alleles wherein those alleles would occur "more frequently than would occur randomly" does not provide a clear and precise definition of the limitation. "Autozygous" and "not autozygous" are understood by the definition provided in the specification and is a term of art. However the limitation is still unclear. There is no indication of a range, threshold or number that one skilled in the art could look for regarding the occurrence of homozygous pairs randomly vs. more frequently. Likewise, it is unclear if the homozygous pairs vary in occurrence depending

on the type of alleles or do all alleles that occur more frequently being considered with respect to a standard occurrence.

Markers are single sequences and cannot be autozygous. Meaning may be attached to particular markers in way of scoring. If that is the case, the claims should be drafted to reflect what a particular single sequence represents and what individual or group of individuals are autozygous.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 11-18 and 21-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing.

The instant claims are drawn to a method of using statistical analysis of genetic data from an inbred population to determine likely genetic regions for a recessive genetic disease or trait. The instant claims are drawn to the abstract process steps of obtaining actual genotype data and estimated genotype data for an inbred population, analyzing actual and estimated genotype data to find a region containing markers exhibiting particular homozygous pairs of alleles by determining first and second scores

of autozygosity, merging scores, computing a ratio of said scores locating a statistically significant gap in sums of merged scores for contiguous regions of markers, selecting from a contiguous region(s) likely to contain a recessive allele associated with the genetic disease, storing the contiguous region to a computer-readable memory and sequencing DNA in at least one contiguous region to identify the recessive allele.

The instant claims do not recite or inherently involve any transformation of an article. The limitation of "sequencing of DNA in said at least one contiguous regions to identify the recessive allele associated with said genetic disease or trait" is an insignificant post solution activity to the abstract process of determining likely genetic regions for a recessive genetic disease or trait. This post solution activity is not given weight as a physical transformation or practical application of the abstract process.

Therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. Instant claim 1 does not recite any limitation that ties the recited abstract process to any particular machine or apparatus. In line 14, of the instant claim 1, claim 11, last line, using a "computing device" for the analyzing step, merging scores, etc. of the abstract process is not a particular machine.

Similarly, claim 21 recites an apparatus comprising a general processor, input and output interfaces and a memory storing instructions executable by the processor. As such, the apparatus is not a particular machine or apparatus, as its only function would preempt the abstract process as set forth above. Further, the two recited input/output terminals only provides input of data and is considered inconsequential.

Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See Ex parte Langemyr (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

Since the instant method claim 1, does not provide a physical transformation, the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 1-8, 11-18, 22 and 23 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of the questionnaire and scoring of answers, to produce a real-world result. The instant claims are drawn to a method of determining likely genetic regions for a recessive genetic disease or trait. However, the last step of the claims includes storing a contiguous region to a computer-readable memory and sequencing a contiguous region. It is

unclear if the computer-readable memory is readable by a user, or if a user would have access to said memory in a tangible form. Likewise, it is unclear if the data produced from the sequencing will be accessible to a user. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

Regarding the system claim 21, because the method claims are drawn to nonstatutory subject matter for not producing a useful, concrete and tangible result, the system that performs the process also does not produce a useful concrete and tangible result, thus also drawn to nonstatutory subject matter. The last instructional step (f) is storing a contiguous region to a computer-readable memory and sequencing DNA.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

For these reasons, claims 1-8, 11-18 and 21-23 are considered non-statutory subject matter.

It is noted that the disclosure does not support the limitation "reported to a user", in the Final Office Action mailed 22 March 2007. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicants argue that amending the instant claims to include "sequencing DNA in said one or more contiguous regions of markers to identify the recessive allele

associated with said genetic disease or trait” provides a useful, concrete and tangible result.

Applicant's arguments are not persuasive.

There is no indication that the identified DNA sequence as a result of sequencing will be accessible to a user. Furthermore, sequencing of a contiguous region is an insignificant post solution activity to the abstract process of determining likely genetic regions for a recessive genetic disease or trait. This post solution activity is not given weight as a physical transformation or practical application of the abstract process.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/
Primary Examiner, Art Unit 1631

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631